

Application No. 10/643,404  
Amendment dated August 2, 2006  
Reply to Office Action of April 20, 2006

4

Docket No.: 59753(48185)

RECEIVED  
CENTRAL FAX CENTER

AUG 02 2006

REMARKS

Claims 1-4 are pending in the instant application. Claims 2 and 3 have been cancelled. Claims 1 and 4 have been amended to more clearly delineate the instant invention. Claim 5 is new. Support for the amendment to claim 1 can be found at least at claim 2 as originally filed and at page 3, line 26 to page 4, line 1 of the application as filed. Support can also be found at claim 3 as originally filed, and at page 11, line 19, through page 12, line 5 of the application as filed. Support for the amendment to claim 4 and support for new claim 5 are found at least at page 1, lines 8-15 of the application as filed. Claims 1, 4, and 5 will be pending upon entry of the instant amendment. No new matter is introduced by these amendments.

Applicants make these amendments without prejudice to pursuing the original subject matter of this application in a later filed application claiming benefit of the instant application, including without prejudice to any determination of equivalents of the claimed subject matter.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-4 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for treating the restenosis or neointimal formation caused by percutaneous transluminal coronary angioplasty (PTCA) or a coronary-artery bypass graft (CABG) with 3-methyl-1-phenyl-2-pyrazolin-5-one, allegedly does not provide reasonable enablement for the term "prevention and/or therapy wall injury" regarding administration of a compound of formula (I).

Applicants disagree and traverse, but have amended claim 1 to include a recitation of compound 3-methyl-1-phenyl-2-pyrazolin-5-one, and have removed the recitation of formula (I). Support for the amendment can be found at least at claim 2 as originally filed and at page 3, line 26 to page 4, line 1 of the application as filed. Additionally, Applicants have added the phrase "arterial wall injury which is caused by coronary angioplasty or coronary-artery bypass graft (CABG)." Support for the amendment is found at least at claim 3 as originally filed, and at page 11, line 19, through page 12, line 5 of the application as filed. The rejection is thus overcome and Applicants request withdrawal of the rejection.

Rejection under 35 U.S.C. § 102(b)

BEST AVAILABLE COPY

Application No. 10/643,404  
Amendment dated August 2, 2006  
Reply to Office Action of April 20, 2006

5

Docket No.: 59753(48185)

Claims 1-4 are rejected as anticipated by Nishi et al. (US 4,857,542). It is alleged that Nishi discloses a method to treat or prevent circulatory disorders. Specifically, it is alleged that the prior art inherently possesses the prophylactic utility in preventing arterial wall injury, including percutaneous transluminal coronary angioplasty (PTCA), coronary-artery bypass graft (CABG), or restenosis or neointimal formation, as disclosed by Applicants.

Applicants disagree and respectfully traverse.

Claim 1 as amended describes a method for prevention and/or therapy of arterial wall injury which is caused by coronary angioplasty or coronary-artery bypass graft (CABG), using 3-methyl-1-phenyl-2-pyrazolin-5-one.

Nishi et al. disclose methods of treating an extremely large number of circulatory disorders [see column 9, line 52 to column 10, line 19], and include at least, various ischemic diseases or various diseases based thereon, cerebrovascular disorders such as cerebral infarction, cerebral apoplexy, etc., various cerebral diseases such as vascular dementia, cerebrovascular tissue lesion, various heart diseases, cardiac insufficiency angina pectoris, etc., and various peripheral circulation disorders, etc. Additionally, Nishi discloses 72 individual pyrazolone derivatives used to treat the extremely large number of possible disorders.

Applicants indicate that one of ordinary skill in the art would not envisage using 3-methyl-1-phenyl-2-pyrazolin-5-one to prevent or provide therapy for an arterial wall injury, which is caused by coronary angioplasty or coronary-artery bypass graft (CABG), based on the laundry list of the at least 72 individual disclosed compounds, the large possible number of compounds of formula (I), and the large number of circulatory diseases provided by Nishi. The MPEP states, in section 2131.02, that,

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated.

BEST AVAILABLE COPY

Application No. 10/643,404  
Amendment dated August 2, 2006  
Reply to Office Action of April 20, 2006

6

Docket No.: 59753(48185)

Additionally, this concept is enunciated in *In re Petering* 301 F.2d 676, 133 USPQ 275 (CCPA 1962), where it was determined that that a generic formula could not anticipate a claim because the generic formula encompassed a vast number of compounds. Further support can be found in *Akzo N.V. v. International Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986), wherein a claim to a specific concentration of a chemical was not anticipated by a disclosure of a general concentration of the chemical.

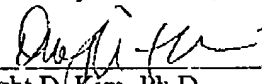
One of ordinary skill in the art would not envisage the utilization of 3-methyl-1-phenyl-2-pyrazolin-5-one, to treat arterial wall injury, based on a reading of Nishi. Regardless of the number of disorders that is recited in the specification, Nishi et al. does not provide for a method of preventing or treating an arterial wall injury. Therefore, at least one element of the claimed subject matter is lacking in Nishi, and Nishi does not anticipate the instant claims. Applicants respectfully request withdrawal of this rejection.

In view of the above remarks, Applicants believe the pending application is in condition for allowance. Should any of the claims not be found to be allowable, the Examiner is requested to telephone Applicants' undersigned representative at the number below. Applicants thank the Examiner in advance for this courtesy.

The Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Attorney Docket No. 48185-59753, Customer No. 21874.

Dated: August 2, 2006

Respectfully submitted,

By   
Dwight D. Kim, Ph.D.

Registration No.: 57,665  
EDWARDS ANGELL PALMER & DODGE  
LLP

P.O. Box 55874  
Boston, Massachusetts 02205  
(617) 439-4444  
Attorneys/Agents For Applicant

RECT AVAILABLE COPY